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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,587	10/24/2003	Si Lok	99-34D1	2256

7590 12/01/2004
Shelby J. Walker
Patent Department
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EXAMINER

BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,587	LOK, SI	
	Examiner	Art Unit	
	Michael D. Burkhardt	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13, 19-24 and 27 is/are allowed.
- 6) ☒ Claim(s) 1, 7, 8, 10, 14-18, 25, 26, 28 and 29 is/are rejected.
- 7) ☒ Claim(s) 2-6 and 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Priority

This application, filed 10/24/2003, is a DIV of 09/704,090, filed 11/01/2000 (now U.S. Paten 6,686,168, issued 2/3/2004), which claims benefit of application 60/163,501, filed 11/4/1999.

Claim Objections

Claims 2-6, and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 (and dependent claims) recites the limitation "translation termination sequence" in lines 1 to 2. There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 10, 25-26, and 28-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Yokoyama-Kobayashi et al (Gene, 1999). The instant claims are drawn to an isolated nucleic acid comprising: a eukaryotic promoter; a type II signal anchor domain; and a cloning site. A cloning site is defined as a sequence that "...allows insertion of a gene or gene fragment." (page 18, lines 8-9 of the specification). The above elements are arranged 5' to 3' in the order listed. The nucleic acid may also comprise a translation termination sequence and a polyadenylation sequence, and these sequences may also be arranged 5' to 3' in the order listed. The claims are also directed to an expression vector, a host cell, and kits comprising the isolated nucleic acid. The host cell may be mammalian. The kit claims contain no further limitations than the parent claims, hence they are anticipated by any reference teaching the parent claims.

Yokoyama-Kobayashi et al disclose an expression vector (pSSD3) comprising the SV40 eukaryotic promoter linked to the HP10085 gene sequence, which is revealed to be the same as the AICL gene sequence (pages 162-163). AICL encodes a type II membrane protein that has a type II signal anchor domain, a stop codon (translation termination sequence) and a polyadenylation sequence (see Genbank entry X96719 or Hamann et al, 1997). The pSSD3 vector was constructed by insertion of HP10085 sequences cut with *HindIII* at the 5' end and one

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of three suitable cloning sites at the 3' end (pg 162, second column, first paragraph). Thus, the vector comprises, in 5' to 3' order, a eukaryotic promoter, a type II signal anchor domain, and a cloning site. The pSSD3 vectors were introduced into COS7 cells (mammalian cells).

Claims 1, 7-8, 10, 25-26, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al (WO98/39476, 1998). The instant claims are as described above.

The Kato reference teaches the base vector (pSSD1) used to construct the pSSD3 vector disclosed in Yokoyama-Kobayashi et al (see Fig. 3 of Kato for a diagram of pSSD1-HP10085). The pSSD1-HP10085 vector thus has the SV40 promoter and all the elements of HP10085 as described above, in the same 5' to 3' order, except the restriction enzymes used for HP10085 insertion were different (*EcoRV*, *EcoRI* pages 9-10 of the English translation). As in the above reference, the expression vector was introduced into COS7 cells (page 10 of the English translation). An English translation of the Kato reference was provided to the applicant during prosecution of the parent application.

Conclusion

Claims 1, 7-8, 10, 14-18, 25-26, and 28-29 are rejected. Claims 2-6, and 9 are objected to and claims 11-13, 19-24, and 27 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER